

REMARKS

Upon entry of this amendment, claims 1-6 and 8-15 will be pending. Claims 1-6 and 8-15 have been amended. Claim 7 has been canceled. Applicants gratefully acknowledge the Office's withdrawal of the previous requirement for an election of species.

The Office has provided suggestions regarding the correction of typographical errors in claims 1 and 9. Applicants have amended claims 1 and 9 in accordance therewith.

Claim Objection

The Office has objected to claims 2-15 under 37 C.F.R. § 1.75(c) for alleged improper dependent form. Applicants have amended the pending dependent claims to insert the word "The" before the phrase "solid dispersions" in each of the objected to claims. Applicants believe that these amendments fully address the objection.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 3, 4, 7, and 8 have been rejected under 35 U.S.C. § 112, second paragraph, for alleged indefiniteness due to the presence of one or both of the trademarks or trade names Eudragit E100 and PVPVA64. Applicants have amended the claims to employ alternative terminology. Specifically, Applicants have amended claims 4 and 6 to replace "Eudragit E100" with the phrase "a cationic polymer based on dimethylaminoethyl methacrylate and neutral methacrylic esters" (*see, e.g.*, U.S. Pat. No. 6,153,220 at col. 1, lines 24-26). Applicants have also amended claims 3, 6, and 8 to replace "PVPVA64" with "a copolymer of vinylpyrrolidone and vinylacetate" (*see, e.g.*, U.S. App. No. 2003/0119901 at paragraph [0049]). Claim 7 has been canceled. Accordingly, Applicants have removed all references to the cited trademarks/trade names in the pending claims, and accordingly respectfully request withdrawal of the rejection of claims 3, 4, and 8.

Rejections Under 35 U.S.C. § 102(b)

Claims 1-3, 5, 8-10, and 12-15 have been rejected as being allegedly anticipated by WO 97/44014 to Baert *et al.* ("the Baert publication"). Although Applicants do not

necessarily concur, they have amended claim 1 to recite preferred dispersions in which the first and second polymers are present in a ratio that is about 70:30 to about 80:20. The Baert publications nowhere teaches or suggests such dispersions. Accordingly, Applicants respectfully submit that the rejection of claims 1-3, 5, 8-10, and 12-15 for alleged anticipation should be withdrawn.

Rejections Under § 103(a)

Claims 1-15 have been rejected under § 103(a) because the claimed subject matter allegedly would have been obvious over WO 02/11694 A2 to Rosenberg *et al.* (“the Rosenberg publication”) in view of the Baert publication or WO 99/33467 to Jung *et al.* (“the Jung publication”). Claims 1-15 also have been rejected under 35 U.S.C. § 103(a) over the Baert publication in view of *Matsumoto & Zografi, Pharm. Res. 16:11 (1999)* (“Matsumoto”) and the Jung publication. However, none of the cited publications discloses or suggests solid dispersions comprising the recited polymers in the recited ratios.

Although the Office contends that the ratio between the first and second polymers “would have been a matter of routine optimization” to one skilled in the art (8/8/2006 Office Action at page 9, first full paragraph), there is no evidence of record suggesting the surprising properties exhibited by the claimed dispersions. As Applicants demonstrate, for example, in FIG. 12, mere combination of the two recited polymers does not, in and of itself, provide the enhanced dissolution properties of the present invention. FIG. 12 shows that when the polymers are combined in a ratio of 60:40 or 20:80, they exhibit an additive effect, *i.e.*, the resulting mixture has an additive dissolution profile in that it lies between the respective dissolution profiles of the individual polymers. However, as shown in FIG. 13, combining the polymers in a ratio of about 70:30 to about 80:20 surprisingly results in a dissolution profile that is not merely additive and, in fact, is superior to either polymer.

Applicants respectfully submit that, as demonstrated at least by these unexpected results, the combination of the first and second polymers at a ratio of about 70:30 to about 80:20 is not obvious over the cited art, and that the rejection of claim 1 and its dependents under § 103(a) should be withdrawn.

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PATENT

In view of the preceding, Applicants respectfully request withdrawal of the rejections of the claims, and further submit that the pending claims are in condition for allowance. If the Examiner has any questions, the Examiner is invited to call the undersigned at (215) 568-3100.

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/S. Maurice Valla/
S. Maurice Valla
Registration No. 43,966

Woodcock Washburn LLP
Cira Centre
2929 Arch Street, 12th Floor
Philadelphia, PA 19104-2891
Telephone: (215) 568-3100
Facsimile: (215) 568-3439